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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,141	01/24/2001	Terri Lynn Stiles	COLLAGEN II NUTRITION 010	3624

7590 01/02/2004

Collagen II Nutrition, Inc.
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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,141	STILES, TERRI LYNN	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on th cover sh t with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21* is/are pending in the application.

4a) Of the above claim(s) *16-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-21* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *January 24, 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status Of Claims

The preliminary amendment filed August 18, 2003 has been entered. **Claims 1-9** were canceled; **Claims 10-15** were amended; and 16-21 were added. **Claims 10-21** are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 10-15, drawn to method of preparation of collagen II containing powder, classified in class 514, subclass 21.

II. Claim 16, drawn to cartilage derived composition comprising polypeptide collagen type II, classified in class 514, subclass 21.

III. Claims 17-21, drawn to method of treating an individual with connective tissue disorder, classified in class 530, subclass 356.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be

prepared by a materially different process such as fermentation, purification and reformulation.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different functions. The invention of Group I is a method of preparation of a polypeptide containing powder where as the invention in Group III is a method of administrating a biological composition for the treatment of connective tissue derived disorders.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, polypeptide collagen type II, can be used in a materially different process such as making antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, searches and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121

does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Kevin C. Ward on October 7, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Responsive to Election of Restrictions

Applicant's election of Invention I, Claims 10-15, in response, filed October 23, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

The current application filed on January 24, 2001 does not claim priority to an earlier application.

Information Disclosure Statement

An IDS has not been filed with the present application.

Specification

The amendment filed January 24, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amount of individual amino acids per grams of protein submitted by table 1 (amino acid composition of Kolla2) of amendment is not the same as the table 1 (amino acid composition of Kolla2) (page 6) of the specification of the application.

Applicant is required to cancel the new matter in the reply to this Office Action.

The use of the trademark Collagen Beauty Protein (COLLAGEN BEAUTY PROTEIN) (page 2, line1) and Collagen Beauty tablets (COLLAGEN BEAUTY TABLETS) (page 2, line 2) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 10** the word "ground" is indefinite. In regards to preparing a biological composition the word "ground" does not necessarily provide for a specific meaning. Since the specification has not defined the word "ground" the meets and bounds of the steps involved in obtaining a "ground" cartilage composition is not defined.

In **claims 12-14** phrase "95 C" is indefinite. The degree symbol is missing applicant needs to insert the symbol " ° " after "95" and before "C".

Claim 13 provides for the use of ethanol, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Alkayali US Patent 6,025,327. Alkayali teaches a method of preparing cartilage derived material comprising collagen type II in a powder form. Alkayali et al. teaches further that mentioned method involves; cutting avian sternal cartilage to within not less than 2 mm of he sternum and removing the cut sternal cartilage from the sternum (column 2, lines 22-25 and lines 49-53) (**present claim 10, step a**), freezing the sternal cartilage (column 2, line 56) (**present claim 10, step b**), cluttering of frozen sternal chicken cartilage (figure 1), (**present claim 10, step c**), suspending the cartilage in an aqueous solution, preferably water (column 2, lines 26-27 and lines 65-66) (**present claim 10, step d and present claim 11**), sterilizing the treated cartilage wherein the sterilizing step is a accomplished by heating the treated cartilage at a minimum of 95° C, for about 30 minutes (**present claim 10, step f and present claim 12**). Alkayali also teaches that the treated sterilized frozen cartilage is hydrolyzed with one or more natural proteases (column 3, page 3-5). It is inherent that as a consequence of hydrolysis of the said frozen, treated sternal cartilage the fat in the composition will also be reduced and hence bringing about a total reduction of the amount of fat - causing a defatting effect (**present claim 10, step g).** Alkayali et al. also includes the following steps of filtering, drying and meshing the treated cartilage in to fine powder (column 3 lines 10-22) (**present claim 10, step h-j and present claim 15).** Thus Alkayali teaches all the elements of **claims 10-12 and 15**) and these claims are anticipated under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkayali US Patent 6,025,327 in view of O' Leary et al. US Patent 5,073,373. Alkayali teaches a method of preparing cartilage derived material comprising collagen type II in a powder form as described above. Alkayali does not teach defatting of treated cartilage using ethanol. O' Leary et al. teach using ethanol for defatting of treated bone compositions (column 2, 14-22). One of ordinary skill in the art would have combined Alkayali and O' Leary et al. for the advantages of a method of preparing cartilage derived material involving defatting of the treated cartilage using ethanol. Ethanol is known in the art to be a good solvent of fat and therefore can be used in a process that requires the removal of fat from a composition. Also it is known that ethanol is a good disinfectant and can destroy contaminants such as microorganisms bacteria and viruses. Given the fact that ethanol is a good solvent of lipids and a more than adequate disinfectant, it would have been obvious to a person of ordinary skill in the art to include the step of deffating using ethanol in the method of preparation of a cartilage derived collagen II composition. As combined, Alkayali and O' Leary et al. demonstrate that one of ordinary skill in the art would

have made and used the claimed invention prior to the time the claimed invention was made. Thus the claimed invention would have been prima facie- obvious at the time it was made.

Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkayali US Patent 6,025,327 in view of Ries US Patent 4,389,487. Alkayali teaches a method of preparing cartilage derived material comprising collagen type II in a powder form as described above. Alkayali does not teach drying, a composition comprising collagen, by heating the composition at a minimum of 95° C for a minimum of 6 hours. Ries teaches drying, a composition comprising collagen, by heating the composition at a minimum of 95° C for a minimum of 6 hours (example 1). One of ordinary skill in the art would have combined Alkayali and Reis for the advantages of a method of preparing cartilage derived material, comprising collagen involving drying by heating the composition at a minimum of 95° C for a minimum of 6 hours. It has been shown that the properties of a composition containing collagen could be substantially improved by treating the composition with heat. The inclusion of this step, also has the benefit of including a second sterilization step that would make the composition more suitable for medical purposes by adhering to GMP guidelines. One skilled in the art would have included a step that improves the properties of collagen and at the same time acts as a sterilization step for the preparation of a collagen containing composition. This sterilization method step has the added benefit of meeting specific GMP guidelines that are required for preparing a composition used for medical purposes. As combined, Alkayali and O' Leary et

al. demonstrate that one of ordinary skill in the art would have made and used the claimed invention prior to the time the claimed invention was made. Thus the claimed invention would have been prima facie- obvious at the time it was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 703-305-4445. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

RBMo
Robert B Mondesi
Patent Examiner
Group 1653
12-28-03

ROBERT A. WAX
PRIMARY EXAMINER